



## **DEPARTMENT OF AGRICULTURE**

### **Animal and Plant Health Inspection Service**

#### **7 CFR Part 340**

**[Docket No. APHIS-2015-0070]**

### **Changes to Requirements for Field Testing Regulated Genetically Engineered Wheat**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of request for comments.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service is seeking public comment regarding plans to require the authorization of field testing of regulated genetically engineered (GE) wheat under permit. Currently, GE wheat field trials are authorized under notification. Authorizing GE wheat field trials under permit will help prevent future compliance issues, protect plant health and the environment, and allow for flexibility in the length of the volunteer monitoring period and the specific permit conditions to address how volunteers of GE wheat will be appropriately managed.

**DATES:** We will consider all comments that we receive on or before **[INSERT DATE 30**

**DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to

<http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0070>.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS-2015-0070, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0070> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Ms. Rachel Windsberg, Lead Management and Program Analyst, Regulatory Operations Programs, BRS, APHIS, 4700 River Road Unit 91, Riverdale, MD 20737; 301-851-3109.

**SUPPLEMENTARY INFORMATION:** The Animal and Plant Health Inspection Service (APHIS) administers regulations regarding genetically engineered (GE) organisms in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests” (referred to below as the regulations). The current regulations govern the introduction (importation, interstate movement, or release into the environment) of certain GE organisms termed “regulated articles.” Regulated articles are essentially GE organisms which might pose a risk as a plant pest. APHIS first promulgated these regulations in 1987 under the authority of the Federal Plant Pest Act and the Plant Quarantine Act, two acts that were subsumed into the Plant Protection Act (PPA, 7 U.S.C. 7701 et seq.) in 2000, along with other provisions.

Certain regulated articles may be introduced into the environment without a permit if developers follow the requirements for authorizations under notification in § 340.3. These requirements include, among other things, that, when the introduction of regulated articles is an environmental release, regulated articles must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release. In addition, the field trial must be conducted such that the regulated article will not persist in the environment, and no offspring can be produced that could persist in the environment.

In 2013 and 2014, APHIS responded to, and investigated, the detection of the unauthorized release of regulated GE wheat found growing in fields in Oregon and Montana, respectively. As part of its response to these incidents, APHIS has carefully assessed its regulatory requirements for field trials of GE wheat and determined that it is necessary to enhance those requirements. Therefore, we are advising the public that we have determined that field trials of GE wheat should be authorized only with a permit. This change will help prevent future compliance issues, protect plant health and the environment, and allow for flexibility in the length of the volunteer monitoring period and the specific permit conditions used to address how volunteers of GE wheat will be appropriately managed. Requiring authorization with a permit also allows APHIS to require the submission of volunteer monitoring reports on a regular basis.

Due to the change in authorization allowed for GE wheat trials, we are requesting public review and comment on this change. To better help us determine specific permit conditions and volunteer monitoring requirements, we are particularly interested in receiving comments regarding biological or ecological issues, and we encourage the submission of scientific data,

studies, or research to support your comments. We also request that, when possible, commenters provide relevant information regarding specific localities or regions as wheat growth, crop management, and crop utilization may vary considerably by geographic region.

After the comment period closes, APHIS will review all written comments received during the comment period. APHIS will notify the public through an announcement on our Web site of the effective date of our decision whether to authorize GE wheat field trials only with a permit and any additional information regarding any change if APHIS decides to authorize wheat only under permits. APHIS will also announce on our Web site information regarding a stakeholder meeting to answer questions from developers on how to comply with this change.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 23<sup>rd</sup> day of September 2015.

**Michael C. Gregoire,**

*Associate Administrator, Animal and Plant Health Inspection Service.*

**BILLING CODE 3410-34-P**

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